U.S.S.N. 08/924,994
Filed: September 5, 1998
AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

It is believed that no additional fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

In the Claims

1. (Twice Amended) A method for determining the level of an apolipoprotein in saliva comprising reacting the apolipoproteins in a saliva sample with antibodies immunoreactive with the apolipoprotein, using [in] a quantitative assay kit comprising means for collection of saliva and antibodies immunoreactive with an apolipoprotein and means for comparing the levels of the apolipoproteins in the saliva with the levels in serum, detecting the amount of immunoreactivity between the antibodies and apolipoproteins in the saliva sample as determined by the quantitative assay, and comparing the amount of determined immunoreactivity with standards of known amounts of apolipoproteins reacted with the antibodies to determine the level of apolipoproteins in the saliva sample.

5. (amended) The method of claim 1 [wherein] further comprising determining the level of apolipoprotein in the saliva sample [is tested] within less than three hours following collection.

6. (twice Amended) The method of claim 1 [wherein] further comprising preparing the saliva in the sample [is prepared prior to testing to remove] by removing mucopolysaccharides from the saliva prior to determining the level of apolipoprotein in the saliva sample.

7. (amended) The method of claim 1 [wherein] further comprising collecting the saliva [is collected] after [stimulation] stimulating its secretion from a subject.

AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

9. (twice Amended) The method of claim 8 further comprising [normalizing] correcting the determined amount of the apoplipoprotein [to the amount] for the presence of albumin [present in the saliva of the individual from whom the saliva was obtained] in the saliva sample.

10. (amended) The method of claim 1 [wherein] further comprising collecting the saliva sample [is collected] into a device which filters out mucopolysaccharides and comprises the antibodies immunoreactive with one or more of the apolipoproteins in the saliva sample.

16. (twice Amended) The assay device or kit of claim 12 wherein the antibodies immunoreactive with apolipoprotein in the saliva sample are immobilized on a solid support.

19. (Amended) The assay device or kit of claim 15 comprising as separate reagents antibodies to [an] the apolipoprotein and antibodies to albumin.

20. (twice Amended) A method for quantitating the amount of lipoprotein or cholesterol in saliva or determining the presence of lipid disorders or risk of cardiovascular disease comprising

(a) reacting the apolipoproteins in a saliva sample with antibodies specifically immunoreactive with apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof in a quantitative assay,

(b) determining the amount of immunoreaction between the antibodies and the apolipoproteins in the saliva sample, and

(c) comparing the amount of immunoreaction determined in step b with the amount of immunoreaction of the antibodies immunoreactive with the apolipoprotein in the saliva sample with known quantities of apolipoprotein in normal or at risk individuals.

21. (amended) The method of claim 1 further comprising,

[determining the correlation between] correlating the levels of HDL and/or LDL in the serum with [and] the levels of [apoprolipoproteins] apolipoproteins in serum, [and]

[determining] correlating the levels of the apolipoproteins in the serum based on the levels of apolipoproteins determined in the saliva sample, and

extrapolating the levels of HDL and/or LDL in the serum, based on the [measurements of the] levels of the apolipoproteins determined in the saliva sample.

22. (amended) The method of claim 20 comprising [quantitating the amount of lipoprotein or cholesterol in saliva or determining the presence of lipid disorders or risk of cardiovascular disease by] reacting [a] the apolipoprotein in the saliva sample with antibodies specifically immunoreactive with an apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof, and

correlating the levels of at least one apolipoprotein in the saliva with the levels of apolipoprotein in serum known to be correlated to [associated with] the presence of lipid disorders or risk of cardiovascular disease.

Please cancel claim 23.

Remarks

Withdrawal of the previous prior art rejections is greatly appreciated.

The claims have been amended as discussed below either to clarify the claims by correcting antecedent basis or utilizing the language suggested by the examiner, or to incorporate